REMARKS

Applicant respectfully requests entry of the Amendment and reconsideration of the claims. New claims 47 to 53 have been added and are supported throughout the specification, including at paragraphs 43-46, 49, 52-54, and 61. The status of claims 43-46 has been corrected to identify the claims as being previously presented. Applicant acknowledges the Examiner's withdrawal of the final rejection of the Office Action dated June 21, 2006 and thereby the rejections under 35 U.S.C. § 103(a). Applicant respectfully requests reconsideration and withdrawal of the pending objection to the claims and rejection under 35 U.S.C. §103(a).

Objections to Claim 43

The Examiner objected to claim 43 on the basis of the use of the term "a voice prosthetic". The Examiner also objected to the claim on the basis that it recites "tubing" twice. Claim 43 has been amended to recite "a voice prosthetic device" and to delete the second reference to "tubing". Applicant respectfully requests removal of these objections to claim 43.

Rejections Under 35 U.S.C. § 103(a)

The Examiner rejects claims 42-46 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Wilcox *et al.* (CA 2,284,364) in combination with Tomita *et al.* (EP 629347) and Johansen (WO 96/06532). To establish a *prima facie* case of obviousness, three criteria must be met--a suggestion or motivation to combine references, a reasonable expectation of success, and the prior art reference teaches or suggests all the claim limitations. MPEP §2143; *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991). Applicant respectfully traverses.

Applicant respectfully asserts that the Examiner has not cited art that teaches or suggests all of the claim limitations. Specifically, the art cited by the Examiner does not teach or suggest ovotransferrin. Hence, combining the three cited references does not produce a composition comprising ovotransferrin and protamine sulfate or a composition comprising ovotransferrin, protamine sulfate, and EDTA as claimed. Applicants respectfully assert that the Examiner has not established a *prima facie* case of obviousness and request removal of this rejection.

Additional Arguments

The Examiner rejects claims 42 to 46 under 35 USC 103(a) as being unpatentable over Willcox et al (CA 2,284,364) taken together with Tomita et al (EP 629347) and Johansen (WO 96/06532). The Examiner stated that Willcox et al. disclose an antimicrobial agent such as lactoferrin for use in coating the surface of a biomedical device. The Examiner stated that Willcox et al. do not teach the use of ovotransferrin and protamine sulfate and EDTA, or ovotransferrin and protamine sulfate in the coatings. The Examiner stated that Tomita et al. disclose an antimicrobial agent comprising lactoferrin hydrolysates, one or more antimicrobial peptides from lactoferrin and one or more compounds selected from the group consisting of metal-chelating protein (e.g. lactoferrin, transferrin, conalbumin) tocopheol, EDTA or a salt thereof and others). The Examiner stated that Tomita et al. also teach that the antimicrobial agent can be used for the treatment of any products or materials. The Examiner stated that Johansen discloses a bacteriocidal or fungicidal composition comprising a basic protein in combination with a cell-wall degrading enzyme or an oxidoreductase, with either protamine or protamine sulfate being used as the basic protein. The Examiner took the position that it would have been obvious for the person skilled in the art to be motivated to combine the three references since its *prima facie* obvious to combine compositions each of which is filed by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.

It is respectfully submitted that the claims are not obvious in view of cited references.

With respect to Willcox, it discloses biomedical devices having at least one surface coated with an effective amount of lactoferrin. As the Examiner has acknowledged, there is not teaching or suggestion of combining the disclosed lactoferrin with another agent have antimicrobial properties, further it does not teach or suggest the use of ovotransferring, protamine sulfate and EDTA or ovotransferrin and protamine sulfate for the preparation of a medical device.

With respect to Tomita, it discloses a number of antimicrobial agents containing lactoferrin hydrosylate and/or antimicrobial peptides derived from lactoferrins in combination with one or more specific compounds including a metal chelating protein (i.e. lactorferrin,

transferrin, conalbumin, casein phosphopetides), tocopherol, cyclodextrin, glycerin-fatty acid ester, alcohol, EDTA and salts thereof. Thus, while Tomita teaches antimicrobial agents which comprise lactoferrin hydrosylate and/or antimicrobial peptides in combination with one or more of specific compounds such as conalbumin (also known as ovotransferrin) or EDTA, there is not teaching or suggestion which motivate the person skilled in the art to prepare an antimicrobial agent comprising solely of selected other "specific compounds". Furthermore, there is no teaching or suggestion in Tomita that would motivate the skilled reader to specifically select ovotransferrin and EDTA for the preparation of an antimicrobial agent over the other "specific compounds" disclosed in Tomita.

With respect to Johansen, it teaches an antimicrobial composition comprising a basic protein or peptide capable of killing microbial cells in combination with a cell-wall degrading enzyme and/or an oxidoreductase. Johansen discloses that basic protein may preferably be protamines or protamine sulfates. While Johansen states that "...it has now been found that protamine is effective against gram-positive bacteria, gram-negative bacteria, and fungi. The same applies for protamine sulphate.", the skilled reader would understand these statements, in the context of the application in its entirety, to refer to the usefulness of the protamine or protamine sulfate in combination with a cell-wall degrading enzyme and/or an oxidoreductase. There is no discussion or suggestion that protamine sulfate alone or in combination with other compounds would be useful for the preparation of an antimicrobial agent. Indeed, Johansen refers to Islam et al which teaches that while protamine inhibits growth of gram-positive bacteria but did not whether the effect was bacteriocidal or bacteriostatic and to Yanagimoto et al which teaches that protamine is not effective against the gram-negative bacteria. Accordingly, the skilled reader having regard to the teachings of Johansen would conclude that an effective antimicrobial composition including protamine or protamine sulfate must also contain a cell-wall degrading enzyme and/or an oxidoreductase. Furthermore, Johnasen discloses that disclosed antimicrobial compositions are useful for the preparation of detergent or cleaning compositions or as preservation agents. There is no teaching or suggestion that the disclosed antimicrobial compositions would be suitable for coating or incorporation into medical device.

The Examiner stated that "it would be have been obvious to the one of ordinary skill in

the art is motivated to combine the three references to use the antimicrobial agent containing lactoferrin, lactoferrin peptides, conalbumin, and EDTA as taught by Tomita and the antimicrobial composition comprising protamine sulfate as taught by Johansen in preparing an antimicrobial agent to coat a surface of a biomedical device such as stents, implants, catheters and opthalmic lenses as taught by Willcox because the antimicrobial agent taught by Tomita contains additional compounds such as EDTA and lactoferrin peptides, conalbumin in addition to lactoferrin the antimicrobial composition taught by Johansen contains protamine sulfate; and it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition to be used for the very same purpose."

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in general knowledge to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference(s) must teach or suggest all of the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not in the Applicant's disclosure, *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); MPEP 2143.

In the present case, the cited prior art fails to provide any motivation to the skilled reader to adapt the teachings of the cited prior art to obtain the claimed invention. As discussed above, both Tomita and Johansen disclose antimicrobial compositions, each of which are comprised of specific combinations of compounds. Tomita teaches antimicrobial compositions comprising lactoferrin hydrosylates/antimicrobial peptides of lactoferrin in combination with one or more other specific compounds. There is no teaching or suggestion to select, out the many "other specific compounds" disclosed, the combination of conalbumin (i.e. ovotransferrin) and EDTA. Also as discussed above, Johansen teaches antimicrobial compositions comprising basic protein or peptide capable of killing microbial cells in combination with a cell-wall degrading enzyme and/or an oxidoreductase. There is no teaching or suggestion in Johansen that protamine sulfate alone or in combination with compounds other than a cell-wall degrading enzyme and/or an oxidoreductase, would be effective as an antimicrobial. Indeed, Johansen acknowledges that

prior to their discovery for combining a basic protein, a cell-wall degrading enzyme and/or an oxidoreductase, the general state of the art suggested that protamine and protamine sulfate were not effective as antimicrobials. Thus, the skilled reader having regard to Johansen would not be motivated to combine protamine sulfate with compounds other than those disclosed in Johansen.

Thus, contrary to the Examiner's assertion, the prior art does not teach or suggest a device having an antimicrobial agent comprising (a) ovotransferrin, protamine sulfate and EDTA or (b) ovotransferrin and protamine sulfate. Willcox only teaches the treatment of medical devices with lactoferrin. Accordingly, it would not be obvious to the person skilled in the art having regard to Tomita, Johansen and Willcox to prepare the medical device of claims 42 to 46. For these reasons, reconsideration and withdrawal of the Examiner's rejection is respectfully requested.

Summary

In view of the above amendments and remarks Applicant respectfully requests a Notice of Allowance. If the Examiner believes that a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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